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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/696,708 | 10/30/2003 | Mark T. Keating | 2323-164 | 7822 |

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| EXAMINER |
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QIAN, CELINE X

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| ART UNIT | PAPER NUMBER |
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1636

| SHORTENED STATUTORY PERIOD OF RESPONSE | NOTIFICATION DATE | DELIVERY MODE |
|--|-------------------|---------------|
| 3 MONTHS | 01/08/2007 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 01/08/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary

Application No.

10/696,708

Applicant(s)

KEATING ET AL.

Examiner

Celine X. Qian Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5,7,9,11,13,15 and 17 is/are rejected.
- 7) ☒ Claim(s) 6,8,10,12,14 and 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 5-17 are pending in the application.

This office action in response to the amendment filed on 10/4/2006.

Response to Amendment

Acknowledgement is made of Applicant's submission of a terminal disclaimer to patent 6,207,383. It has been approved. The rejection of claims 5-10 for double patenting has been withdrawn.

The restriction between different primer sequences has been withdrawn and the objection to claims 6, 8 and 10 has been withdrawn.

The rejection of claims 5, 7, 9 under 35 U.S.C.102 (b) is maintained for reasons set forth of the record mailed on 4/21/06 and further discussed below. Claims 11, 13, 15 are also rejected by the same reference for reasons given below.

Claims 11, 13, 15 and 17 are also rejected under 35 U.S.C. 102 (a) for reasons given below. This is a new rejection necessitated by Applicant's amendment.

Claims 5-10 and 17 are rejected under 35 U.S.C. 112 1st paragraph for reasons given below. This is a new rejection necessitated by Applicant's amendment.

Response to Arguments

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 5, 7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Keating et al.

In response to this rejection, Applicants argue that Keating discloses a genomic characterization of HERG having only three introns and 4 exons, whereas the present invention discloses 15 exons. Applicants further assert that the primers listed in Table 1 cannot be used to amplify entire exon except for exon 7. Applicants thus conclude that the amended claims are not anticipated by the reference.

The above arguments have been fully considered but deemed unpersuasive. The instant claims are drawn to a method of detecting a mutation which causes or is associated with LQT by amplifying any one of exons 1-6 and 8-15 of HERG with a pair of primers that amplify the entire exon. The Keating reference discloses a number of mutations identified by amplification of different exons, i.e., exon 1, 2 (mutation in S2 is located in exon 1, and mutation in S5 is located in exon 2), see Figure 12 G-I. Further, the intron/exon boundary is also disclosed in Keating et al. (see Figure 9, legend, col.4). While the primer for amplifying the entire exon is not disclosed in Table 1, the disclosure of the Keating enables one to make such primers since the cDNA sequence and boundary of exon/intron is known. The claim is directed to a method of amplifying any one of the exons from 1-6 and 8-15, the claim limitation does not require any specific primer sequence. As such, it does not require the reference to teach a specific primer sequence that is able to amplify the entire exon to anticipate that instant claimed invention. Therefore, the teaching of Keating et al. discloses every limitation of the claims. The rejection is thus maintained.

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Claims 11, 13 and 15 are also anticipated by this reference because the reference has taught amplifying mutant sequence in different exons (see discussion above). Thus, it discloses a method of detecting a mutation which causes or is associated with LQT by amplifying two or more exons from 1-15 of HERG with a pair of primer that amplifies the entire exon. Similarly, since no specific primer is recited in the claim, the reference does not have to teach a specific primer sequence. The disclosure of the Keating is sufficient to anticipate the instantly claimed invention.

New Grounds of Rejection Necessitated by Applicant's Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-10 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 5 is amended to recite amplifying any one of "exons 1-6 and 8-15 of HERG." This newly added limitation is not supported by the instant specification. The instant specification does not teach a method for detecting a mutation which causes or is associated with LQT by amplifying the any one of the specific exons (without exon 7). Thus, such recitation

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constitutes new matter. Claims 6-10 are also rejected for containing new matter because they depend on claim 5.

Claim 17 recites amplifying all 15 exons of HERG. This limitation is not disclosed in the cited paragraph 49, 163, 192 and 193 of the instant specification. The cited paragraph only discloses amplifying regions within HERG for mutation, not entire 15 exon with no other sequence as recited by the instant claim. Therefore, such recitation constitute new matter.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 11, 13, 15 and 17 are rejected under 35 U.S.C. 102(a) as being anticipated by Itoh et al (Human Genetics, 1998, Vol 102, pages 435-439).

The claims are drawn to a method of detecting a mutation which causes or is associated with LQT by amplifying two or more exons from 1-15 of HERG with a pair of primer that amplifies the entire exon.

Itoh et al. discloses a method of detecting a mutation which causes or is associated with LQT by amplifying two or more exons from 1-15 of HERG with a pair of primer that amplifies the entire exon. Itoh et al. discloses all intron/exon boundary of the 15 exon, and primers for amplifying all 15 exon (see Figure 1). Itoh et al. further discloses mutations detected in different region (see Table 1). Therefore, Itoh et al. disclose the instantly claimed inventions.

Claim Objections

Claims 6, 8, 10, 12, 14 and 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Celine X Qian Ph.D.
Examiner
Art Unit 1636

CELINE QIAN, PH.D.
PRIMARY EXAMINER

